

March 8, 2002 4 2 72 PM -8 FAX

Ms. Margaret M. Dotzel
Associate Commissioner for Policy
United States Food and Drug Administration
Dockets Management Branch (HFA-305)
5630 Fishers Lane
Room 1061
Rockville, Maryland 20852

Re: FDA Food Security Guidance, Docket 01D-0583

Dear Associate Commissioner Dotzel:

These comments relating to the Food and Drug Administration's ("FDA") guidance document titled "Food Producers, Processors, Transporters, and Retailers: Food Security Preventive Measures Guidance" are submitted on behalf of the National Association of Convenience Stores ("NACS"). Founded in 1961, NACS is a non-profit trade association representing more than 2,200 retail and 1,400 supplier company members in the United States and abroad. Retail members operate nearly 80,000 convenience stores. Seventy percent of NACS members are mom and pop shops, operating ten stores or less. These retailers provide consumers with convenient locations to quickly purchase a wide array of products and services, including prepared foods, baked goods, snack foods, soda, and candy. Collectively, foods and beverages accounted for nearly 50 percent of in-store sales by convenience stores in 2000. Convenience stores also sell motor fuels and automotive products such as motor oil and fuel additives. In addition, many convenience stores are small businesses that operate with tight profit margins on many of the products they sell. Increased compliance costs may erode profit margins and require convenience stores to re-evaluate the products they offer.

NACS believes that FDA's guidance document points out issues and practices that are appropriate to apply to many entities in different sectors of the food business. Many individual recommendations, however, are not appropriately applied to convenience stores. The FDA recognizes that "[n]ot all of the guidance contained in [the guidance] document is appropriate or practical for every food establishment." While the FDA recognizes this fact, the guidance document still groups together many different food businesses (including producers, processors, transporters and retailers) and leaves to each individual entity the task of deciding which provisions apply to it. In some cases this is easy. In many cases, however, it is difficult to determine whether a particular guidance measure should be followed and how it should be followed.

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This comment letter discusses each of the sections of FDA's guidance document that include the particular recommendations that are most troubling to NACS. NACS recognizes that the guidance document is intended to cover many diverse food establishments, but we are concerned that this approach does not sufficiently inform establishments of the measures FDA would like them to implement. Even though the guidance document is not legally binding on food establishments, NACS is concerned that courts, in the context of any civil litigation, would interpret the guidance as FDA's position regarding responsible compliance practices. As a result, there can be serious legal ramifications if the guidance is unclear or not practical to follow. Accordingly, NACS requests that FDA define the smaller universe of recommendations that are appropriate and practical for convenience stores, and clarify the recommendations that need further explanation.

1. Management of Food Security

Some of the FDA guidance relating to food security management would be impractical for convenience stores to follow. For example, FDA calls for immediate investigation of "all information about suspicious activity." Many convenience stores, however, do not have the staff resources to abandon their normal duties to perform an investigation. Often, one employee works alone in the store. It is not practical for that individual to undertake an immediate investigation.

Staff resources also make it difficult for convenience stores to conduct daily security checks of their premises. Because many stores operate for 24 hours -- often with one person on duty at a time -- this would require additional staffing and could be disruptive to customer service.

In addition, FDA guidance includes some items that need clarification to determine whether they can reasonably be followed. For example, food establishment operators are told to consider giving security responsibility to "qualified individual(s)," but the guidance does not include any information about the types of individuals FDA considers to be "qualified." Given the limited staffing of convenience stores it may be difficult to implement this recommendation if FDA expects a high degree of expertise in security issues.

FDA's note that employers should provide an "appropriate level of supervision to all employees" also needs clarification. There is no guidance regarding what FDA considers to be "appropriate." Convenience stores do provide the level of supervision that is appropriate to the efficient conduct of their businesses, but that does not mean that employees are constantly supervised while on the job -- especially in stores that are open 24 hours a day.

2. Physical Facility

FDA guidance regarding physical facilities has a number of items that should not be applicable to convenience stores. NACS believes these items have been included in the guidance document because they are applicable to other food businesses, but clarification from FDA regarding these recommendations would be helpful. With regard to visitors, for example, FDA recommends “restricting entry to the establishment” and “restricting access to food handling and storage areas” including for customers. Of course, convenience stores and many of their food handling and storage areas are specifically designed to be easily accessible to the public. This convenience is, in fact, a foundation of a store’s business. These items should not be applied to convenience stores.

Similarly, guidance document recommends protecting perimeters with fencing or other deterrents, using security patrols and video surveillance, and having a system to control vehicles authorized to park on the premises. None of these requirements make sense for convenience stores. Convenience stores typically have many vehicles driven by customers on their premises to buy motor fuels and/or make in-store purchases. Protecting perimeters and controlling vehicle access would be completely anathema to these businesses. While some convenience stores use video surveillance as a security tool, this is too costly for many small businesses. Security patrols are not economically feasible for convenience stores.

In addition, some of the guidance relating to physical facilities and the storage of hazardous chemicals needs clarification. These recommendations include:

- securing storage areas for hazardous chemicals (e.g., using locks, seals, alarms, intrusion detection sensors, guards, monitored video surveillance [remember to consult any state or local fire codes that may apply before making any changes]);
- limiting access to storage areas for hazardous chemicals.

The guidance document does not define what it considers to be “hazardous chemicals.” If these include motor fuels, fuel additives sold at retail, motor oil and other substances common to many convenience stores, then these provisions would fundamentally alter the business of this industry. Convenience stores keep many such items on shelving and product displays accessible to its customers. The public also has direct access to motor fuels at self-service pumps. It is not clear what FDA expects businesses to do in response to these recommendations, but they should not inhibit the public’s access to products sold by convenience stores.

3. Employees

The guidance document recommends screening employees by verifying references and conducting criminal background checks for all employees -- including temporary or seasonal workers. While this may be reasonable in some cases, conducting criminal background checks triggers employer responsibilities under federal, state and local law. It would be overly burdensome for many employers to conduct such checks -- especially for those located in states with particularly stringent privacy and related legislation. For convenience stores, these procedures would be particularly burdensome for some classes of employees because the rate of employee attrition in those jobs is high and, as a result, convenience stores would incur large costs that will not be recouped because many employees will not stay in the job for long. On average, store clerks attrition rate is nearly 160% and store managers is nearly 100%.

Some of the guidance does not make sense given the facilities for most convenience stores. For example, the guidance document recommends:

- establishing a system of positive identification and recognition (e.g., issuing photo identification badges with individual control numbers, color coded by area of authorized access), and
- limiting access so employees enter only those areas necessary for their job functions.

Convenience stores are small operations and employees typically need access to all areas of the business in order to do their jobs. Because of the small number of staff at most convenience stores it also does not make sense to implement an identification and recognition system. These recommendations should not apply to convenience stores.

4. Raw Materials and Packaging

It seems clear that FDA's guidance relating to raw materials and packaging was not written with convenience stores in mind. Some of these provisions would be problematic if they applied to convenience stores. For example, the guidance document states that food establishment operators should consider:

- taking steps to ensure that suppliers and transporters practice appropriate food security measures;
- authenticating labeling and packaging configuration in advance of receipt of shipment;
- evaluating the utility of testing incoming ingredients;

- requesting locked and sealed vehicles/containers/railcars, obtaining the seal number from the supplier, and verifying upon receipt;
- establishing quarantine and release procedures.

These measures would be very burdensome for convenience stores. Convenience stores do not have the means to ensure that their suppliers take the right security measures nor do they have the leverage (or the need) to request sealed containers and the like. Instead, the responsibility to employ proper security and transportation practices must lie with the supplier or transporter. Similarly, convenience stores do not have the resources or expertise to authenticate labels and test ingredients. These requirements do not make sense for small businesses like those in this industry. It is also unclear what quarantine and release procedures are contemplated by the guidance document. NACS believes that FDA should clarify that these measures do not apply to convenience stores.

5. Operations

The guidance document divides its recommendations regarding operations into two categories: security of water and security of air. Both categories seem geared to major industrial operations -- not convenience stores. Some of the provisions include testing for water potability, chlorinating water systems, identifying alternative sources of potable water, securing access to air intake points for the facility, and routinely examining air intake points for physical integrity. Each of these requirements is outside the bounds of practicality for convenience stores.

6. Finished Products

Some of the finished product recommendations are very similar to the raw materials recommendations. For example, requesting locked and sealed vehicles/containers/railcars, ensuring that warehousing and shipping vehicles practice appropriate security, inspecting storage facilities and vehicles, and testing finished products were also provisions of FDA's raw materials recommendations. These recommendations are equally inappropriate for convenience stores in the context of finished products as they are in the context of raw materials.

7. Security Strategies

One security strategy presents difficulties if it is applied to convenience stores -- maintaining a floor or flow plan in a secure, off-site location. Some convenience stores simply do not have such an off-site location for this purpose and, given the size of most stores, the recommendation seems unnecessary.

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8. **Evaluation**

The guidance document states that food establishment operators should have evaluation programs for their security systems that should include annually reviewing and testing their systems using third party or in-house security experts, and performing routine and random food security inspections using third party or in-house security experts. These provisions would be very difficult for convenience stores to follow. Convenience stores typically do not have the resources to employ in-house or third party security experts. It would be helpful for FDA to recognize that these provisions should not be applied to convenience stores.

Conclusion

Many of the recommendations in FDA's guidance document are not appropriate for convenience stores and many others need clarification so that businesses can evaluate their practicality. Even though the guidance document is not legally binding on food establishments NACS is concerned that courts, in the context of any civil litigation, would interpret the guidance as FDA's position regarding responsible compliance practices. As a result, there can be serious legal ramifications if the guidance is unclear or not practical to follow. Accordingly, NACS requests that FDA define the smaller universe of recommendations that are appropriate and practical for convenience stores and clarify the recommendations identified in this letter as needing further explanation.

Thank you for your consideration.

Sincerely,

A handwritten signature in black ink, appearing to read "A. R. Shulman".

Allison Shulman
Director, Government Affairs